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EXAMINER	
HOLBROOK, PAMELA G	

ART UNIT	PAPER NUMBER
1647	5

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/885,537	Applicant(s) SPECTOR ET AL.	
	Examiner Pamela G Holbrook	Art Unit 1647	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2,5-17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. The use of the trademark Bio-Gide has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1,2, 5-7, 9-11 and 13 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Shimizu [US Patent 6090117 (Jul. 18, 2000)].

Claim 1 is drawn to a nerve regeneration tube with a resorbable sidewall comprised of collagen material, the sidewall having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells there through, the sidewall of the tube further having a fibrous inner surface opposite the smooth barrier surface.

Shimizu teaches "an artificial tube for nerve which comprises a tube or having coating layers or composed of gelatin or collagen on the inner and outer surfaces of a tube" [column 2, line 41] and "inserting a collagen fiber bundle so as to be substantially parallel to the axis of said tubes" [column 2, line 56]. Shimizu clearly anticipates the invention of claim 1.

Claim 2 is drawn to the tube of claim 1, wherein said sidewall is comprised of a mixture of type III and type I collagen.

Shimizu teaches "coating layers composed of collagen formed on the inner and outer surfaces of this tube use conventional solubilized type I collagen or a mixed collagen of type I and type III" [column 5, lines 4-7]. Shimizu clearly anticipates the invention of claim 2.

Claims 5 and 7 are drawn to the tube of claim 1, containing a filling material comprised of type I collagen and/ or type IV collagen, or a mixture there of.

Shimizu teaches an artificial tube for nerve and that "a collagen body within its lumen is a crosslinked collagen fiber bundle" [column 5, lines 31-32] and that "it is preferable that the collagen fiber bundle be type I collagen fibers" [column 5, line 41] and, in addition that a matrix gel is filled into cavities between collagen fibers" [column 8, lines 40-43], "the matrix gel containing extracted collagen (and particularly type IV collagen) [column 8, line 47]. Shimizu clearly anticipates the invention of claims 5 and 7.

Claim 6 is drawn to the tube of claim 5, wherein the filling material is comprised of collagen fibers having a substantially longitudinal orientation with respect to said tube.

Shimizu teaches "inserting a collagen fiber bundle so as to be substantially parallel to the axis of said tubes" [column 2, line 56-58]. Shimizu clearly anticipates the invention of claim 6.

Claim 9 is drawn to the tube of claim 5, wherein said filling material further includes a nerve growth stimulant, nerve growth factor or a mixture there of.

Shimizu teaches "a matrix gel containing components that promote nerve fiber growth [column 8, line 39-40] including nerve growth factor" [column 8, line 52]. Shimizu clearly anticipates the invention of claim 9.

Claim 10 is drawn to the tube of claim 9, wherein said filling material contains laminin as a nerve growth stimulant.

Shimizu teaches "a matrix gel containing components that promote nerve fiber growth [column 8, line 39-40] including laminin" [column 8, line 48]. Shimizu clearly anticipates the invention of claim 10.

Claim 11 is drawn to the tube of claim 1, wherein said sidewall is derived from collagen membrane tissue.

Shimizu teaches "collagen originating in various animals conventionally used in the past can be used for the collagen raw material preferable examples of which include type I and type III collagen originating in the skin, bone cartilage, tendon and organs of cows, pigs, rabbits, sheeps, kangaroos or birds" [column 4, lines 32-37]. Shimizu clearly anticipates the invention of claim 11.

Claim 13 is drawn to a nerve regeneration tube with a sidewall comprising collagen material derived from collagen membrane tissue.

Shimizu teaches "collagen originating in various animals conventionally used in the past can be used for the collagen raw material preferable examples of which include type I and type II collagen originating in the skin, bone cartilage, tendon and organs of cows, pigs, rabbits, sheeps, kangaroos or birds" [column 4, lines 32-37]. Shimizu clearly anticipates the invention of claim 13.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu [US Patent 6090117 (Jul. 18, 2000)] as applied to claims 1,2, 5-7, 9-11 and 13, above, and further in view of Tonge et al. [Experimental Neurology 146, 81-90 (1997)].

Claim 8 is drawn to a nerve regeneration tube, wherein the Type I collagen and Type IV collagen of the filling material is in a ratio of about 1:1 by weight.

Shimizu teaches as filling material "a matrix gel containing components that promote nerve fiber growth" [column 8, line 39-40].

Shimizu fails to teach a filling material comprised of Type I collagen and Type IV in a ratio of about 1:1 by weight.

Tonge et al. teach that axonal growth was consistently better in matrigel than in Type I collagen (page 81, column 2, 3rd paragraph) and that matrigel contains (as a proportion of protein by weight) 31% type IV collagen [page 84, column 2, 1st paragraph].

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Shimizu and Tonge et al. to use a filling material comprised of Type I collagen and Type IV in a ratio of about 1:1 by weight, in order to facilitate nerve regeneration.

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu [US Patent 6090117 (Jul. 18, 2000)] as applied to claims 1,2, 5-7, 9-11 and 13, above, and further in view of Geistlich et al. [US Patent 5837278 (Nov. 17, 1998)].

Claim 12 is drawn to the tube of claim 11 wherein said membrane tissue is peritoneal tissue.

Shimizu teaches "an artificial tube for nerve which comprises a tube or having coating layers or composed of gelatin or collagen on the inner and outer surfaces of the tube" [column 2, line 41-44].

Shimizu fails to teach that said membrane tissue is peritoneal tissue.

Geistlich et al. teach a resorbable collagen membrane for use in guided tissue regeneration comprising a membrane derived from mammalian peritoneum [column 7, line 35-36].

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to combine the methods of Shimizu and Geistlich et al. to produce a tube from a sheet of collagen material derived from mammalian peritoneum and one would have been motivated to do so with a reasonable expectation of success, in order to facilitate nerve regeneration.

Claim 14 is drawn to the tube of claim 13 wherein said collagen membrane tissue is peritoneal membrane tissue.

Shimizu teaches "an artificial tube for nerve which comprises a tube having coating layers or composed of gelatin or collagen on the inner and outer surfaces of the tube" [column 2, line 41].

Shimizu fails to teach that said membrane tissue is peritoneal membrane tissue.

Geistlich et al. teach a resorbable collagen membrane for use in guided tissue regeneration comprising a membrane derived from mammalian peritoneum [column 7, line 35-36].

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to combine the methods of Shimizu and Geistlich et al. to produce a tube from a sheet of collagen material derived from mammalian peritoneal membrane tissue and one would have been motivated to do so with a reasonable expectation of success, in order to facilitate nerve regeneration.

Claims 15-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu [US Patent 6090117 (Jul. 18, 2000)] as applied to claims 1,2, 5-7, 9-11 and 13, above, and further in view of Stensaas et al. [US Patent 4778467 (Oct. 18, 1988)].

Claim 15 is drawn to a method of producing a nerve regeneration tube using a sheet of collagen material and forming said sheet into a tube.

Shimizu teaches "an artificial tube for nerve which comprises a tube having coating layers or composed of gelatin or collagen on the inner and outer surfaces of the tube" [column 2, line 41]

Shimizu fails to teach production of the nerve regeneration by forming a tube from a collagen sheet.

Stensaas et al. teach a tubular prosthesis for promoting nerve regeneration made of a sheet of biocompatible material [column 2, line 13-19; Figures 1, 3A, 3B].

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to combine the methods of Shimizu and Stensaas et al. to produce a tube from a sheet of collagen material by forming said sheet into a tube and one would have been motivated to do so with a reasonable expectation of success, in order to facilitate nerve regeneration.

Claim 16 is drawn to the method of claim 15, wherein said sheet of collagen material has two opposite side edges, and the two side edges of said sheet are brought together to form said tube from said sheet.

Shimizu teaches "an artificial tube for nerve which comprises a tube having coating layers composed of gelatin or collagen on the inner and outer surfaces of the tube" [column 2, line 41]

Shimizu fails to teach production of the nerve regeneration from a sheet of collagen, wherein said sheet of collagen material has two opposite side edges, and the two side edges of said sheet are brought together to form said tube from said sheet.

Stensaas et al. teach a tubular prosthesis for promoting nerve regeneration made of a sheet of biocompatible material [column 2, line 13-19] that has two opposite side edges that are brought together to form said tube from said sheet [13-19 Figures 1, 3A, 3B].

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to combine the methods of Shimizu and Stensaas et al. to produce a tube from a sheet of collagen material that has two opposite side edges by bringing said side edges together to form a tube and one would have been motivated to do so with a reasonable expectation of success, in order to facilitate nerve regeneration.

Claim 17 is drawn to the method of claims 16, further including a step of joining said two edges together to form said tube from said sheet.

Shimizu teaches "an artificial tube for nerve which comprises a tube having coating layers composed of gelatin or collagen on the inner and outer surfaces of the tube" [column 2, line 41]

Shimizu fails to teach joining two side edges of a collagen sheet together to form a tube.

Stensaas et al. teach that the prosthesis has a gap and that the walls of the prosthesis close to form a relatively tight seal" [column 9, line 1-14].

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to combine the methods of Shimizu and Stensaas et al. to join the two side edges of the collagen sheet together to form a tube and one would have been motivated to do so with a reasonable expectation of success, in order to facilitate nerve regeneration.

Claim 19 is drawn to the method of claim 15, wherein said sheet is formed into said tube with a filling material in said tube comprised of type I, type IV collagen or a mixture thereof.

Shimizu teaches an artificial tube for nerve and that "a collagen body within its lumen is a crosslinked collagen fiber bundle" [column 5, lines 31-32] and that "It is

preferable that the collagen fiber bundle be type I collagen fibers" [column 5, line 41] and, in addition that a matrix gel is filled into cavities between collagen fibers" [column 8, lines 40-43], "the matrix gel containing extracted collagen (and particularly type IV collagen) [column 8, line 47]. Shimizu clearly anticipates the invention of claims 5 and 7.

Shimizu fails to teach production of the nerve regeneration by forming a tube from a collagen sheet.

Stensaas et al. teach a tubular prosthesis for promoting nerve regeneration made of a sheet of biocompatible material [column 2, line 13-19] that is formed into a tube [Figures 1, 3A, 3B].

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to combine the methods of Shimizu and Stensaas et al. to produce a tube from a sheet of collagen material with a filling material comprised of type I, type IV collagen or a mixture thereof and one would have been motivated to do so with a reasonable expectation of success, in order to facilitate nerve regeneration.

Claim 20 is drawn to the method of claim 15, wherein said sheet has two opposite sides which are overlapped to form said tube.

Shimizu teaches "an artificial tube for nerve which comprises a tube having coating layers composed of gelatin or collagen on the inner and outer surfaces of the tube" [column 2, line 41]

Shimizu fails to teach production of a nerve regeneration tube from a collagen sheet wherein said sheet has two opposite sides which are overlapped to form the tube.

Stensaas et al. teach a prosthesis that has an inner longitudinal edge and an outer longitudinal edge that overlap [column 16, line 61-62; Figures 7A and 7B].

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to combine the methods of Shimizu and Stensaas et al. to produce a tube from a sheet of collagen material by overlapping the two opposite sides and one would have been motivated to do so with a reasonable expectation of success, in order to facilitate nerve regeneration.

Claim 21 is drawn to the method of claim 20, wherein said sheet is formed into said tube with a filling material in said tube comprised of type I collagen, type IV collagen or a mixture thereof.

Shimizu teaches an artificial tube for nerve and that "a collagen body within its lumen is a crosslinked collagen fiber bundle" [column 5, lines 31-32] and that "It is

preferable that the collagen fiber bundle be type I collagen fibers" [column 5, line 41] and, in addition that a matrix gel is filled into cavities between collagen fibers" [column 8, lines 40-43], "the matrix gel containing extracted collagen (and particularly type IV collagen) [column 8, line 47]. Shimizu clearly anticipates the invention of claims 5 and 7.

Shimizu fails to teach production of a nerve regeneration tube from a collagen sheet wherein said sheet has two opposite sides which are overlapped to form the tube.

Stensaas et al. teach a prosthesis that has an inner longitudinal edge and an outer longitudinal edge that overlap [column 16, line 61-62; Figures 7A and 7B].

Thus it would have been *prima facie* obvious to one of ordinary skill in the art to combine the methods of Shimizu and Stensaas et al. to fill the tube, produced by overlapping the two opposite sides of a collagen sheet, with a material comprised of type I collagen, type IV collagen or a mixture thereof and one would have been motivated to do so with a reasonable expectation of success, in order to facilitate nerve regeneration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pamela Holbrook whose telephone number is (703) 306-3221, Mon.- Fri. 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Gary L. Kunz

GARY L. KUNZ
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